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The ECDC: Challenges during and after the Covid-19 pandemic

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ABSTRACT. *This policy brief analyses the challenges confronting the European Centre for Disease and Control (ECDC) during the pandemic and the extent to which the newly adopted regulation on strengthening the Centre addresses them. The pandemic has magnified the endemic design flaws of the EU's health security framework.*

The ECDC faced numerous challenges during the pandemic. First, it struggled to oversee fundamental disease surveillance in due time, partly due to member states' incomplete, incomparable, and at times delayed data reporting to the Centre. Second, it took a rather reactive and cautious approach instead of a more proactive response with practical hands-on advice and support to member states based on best available evidence. Third, it interpreted its mandate strictly as a risk assessing agency rather than that of risk management.

The Centre's strengthened mandate seeks to address these shortcomings. The updated regulation, informally agreed upon in November 2021, includes plans for state-of-the-art disease surveillance, improved preparedness, and response planning with member states, and stronger ECDC guidance before and during emergencies. The ECDC's ability to formulate country-specific recommendations and options for risk management show that the EU is slowly moving into the area of risk management, previously considered a no-go area by member states.

The updated regulation does not solve all the problems facing the ECDC during the pandemic, not least because public health remains a national prerogative. As long as the ECDC relies on the member states' goodwill to share key surveillance data, challenges to the quality of the ECDC's epidemiological surveillance is likely to persist, including delays in risk assessment and management. Plans to roll-out a more digitalised surveillance system (e.g., a European Health Data Space) is a massive endeavour that will not be in place for some time.

Introduction

When the central government of China put Wuhan and several other Chinese cities in Hubei into lockdown on 23 January 2020, the European Centre for Disease and Control (ECDC) concluded that the risk of spread to Europe was low. At the same time, the European Commission stated that EU member states were prepared should the virus spread to Europe.

On 24 January 2020, the first Covid-19 case was discovered in France. A few weeks later, on 11 March 2020, the World Health Organisation (WHO) declared Covid-19 a Public Health Emergency of International Concern and confirmed that Europe was the centre of it. Within a few weeks, a small EU agency with no regulatory powers in Stockholm, unknown to most Europeans, was thrown into the spotlight and put to the test. Covid-19 is the biggest and most prolonged public health emergency the ECDC has encountered and the first pandemic to impact Europe at scale.

No one in Europe - not even the ECDC - anticipated how fast a virus coming from Asia could spread to the rest of the world. The EU failed to detect the spread of the virus in Europe in due time and lacked the necessary risk management tools to deal with it. Member states struggled with inadequate stockpiling of medical and personal protection equipment (PPE), shortages of qualified medical staff, insufficient hospital beds, and limited testing and contact tracing capacity, stretching health care systems to the limit. The pandemic has magnified the endemic design flaws of the EU's health security framework - not least because public health is a national prerogative, where the EU can only seek to coordinate (but not regulate) national efforts.

Covid-19 has certainly changed the salience of public health and increased member states' willingness to strengthen the EU's health security framework – albeit within the narrow confines of the Treaties. The European Commission was quick to take advantage of this new window of opportunity to boost the EU's role in public health. In November 2020, it put forward a health package to address some of the challenges facing the EU during the first year of the pandemic. The package consists of three main pillars: (1) a regulation on serious cross-border health threats, (2) a reinforcement of the EU's existing agencies in public health, the ECDC and the European Medicines Agency (EMA), and (3) the establishment of the European Health Emergency Preparedness and Response Authority (HERA) to ensure timely access to medical countermeasures in cross-border health crises.

This policy brief focuses on the ECDC, as one pillar of the EU's health security framework, and analyses the challenges the ECDC faced during the pandemic and the extent to which the newly adopted ECDC regulation addresses them. The policy brief consists of three

parts: the role of the ECDC prior to the Covid-19 crisis, the ECDC's performance during the pandemic, and the changes introduced to its mandate and mission.

The ECDC before Covid-19

The ECDC was established in 2005 with the mission to (1) identify, assess, and communicate current and emerging threats to human health from infectious diseases, (2) support preparedness planning and response, and (3) offer training and scientific advice to member states and the European Commission. [1]

The ECDC oversees health risk surveillance by monitoring the risk to human health from communicable diseases, in a field already crowded by more powerful players, i.e., national authorities and the World Health Organisation (WHO).[2] The ECDC does not have a mandate to engage in risk management. Risk management and the decisions to adopt pharmaceutical (e.g., vaccines) or non-pharmaceutical (e.g., containment and mitigation measures) interventions remain a national competence. Instead, the ECDC's role is to inform, guide, and recommend rather than to interfere with national public health responses. The Centre has a reputation of excellence due to its scientific and technical expertise, but its role is restricted to assessing and monitoring the risk posed by infectious diseases.[3]

The creation of the ECDC was partly a result of the learnings done during the EU's uncoordinated and inefficient response to the severe acute respiratory syndrome (SARS) outbreak in 2003[4]. However, the idea of creating a European centre for disease control was already aired in medical journals among infectious disease specialists in the late 1990s.[5] It got the attention of the EU's heads of state and government in June 2001 when the idea of a European centre in public health was first mentioned in the European Council conclusions.[6]

[1] Regulation (EC) No 851/2004 of the European Parliament and the Council of 21 April 2004 Establishing a European Centre for Disease Prevention and Control, available at https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=celex%3A32004R0851 (accessed 13 December 2021)
[2] Deruelle, T. (2021). A Tribute to the Foot Soldiers: European Health Agencies in the Fight Against Antimicrobial Resistance, *Health Economics, Policy, and Law,* 16(1), 23-37
[3] Beaussier, A. & Cabane, L. (2020). Strengthening the EU's Response Capacity to Health Emergencies: Insights from EU Crisis Management Mechanisms, *European Journal of Risk Regulation*, 11, 808-20.
[4] Greer, S.L. (2012). The European Centre for Disease Prevention and Control: Hub or Hollow Core, *Journal of Health Politics, Policy and Law*, 37(6), 1001-1030
[5] Deruelle, T. & Engeli, I. (2021). The COVID-19 crisis and the rise of the European Centre for Disease Prevention and Control (ECDC), *West European Politics*, 44(5-6), 1-25
[6] European Council (2001). Presidency Conclusions – Göteborg European Council, 15 and 16 June 2001, p.7, point 20, available at https://www.consilium.europa.eu/media/20983/00200-r1en1.pdf (accessed 13 December 2021).

The SARS outbreak did not radically change the EU's role in public health but played a catalytic role in formalising existing informal networks.[7] The ECDC's establishment marks a formal institutionalisation of two existing informal networks: the communicable diseases network and the 'charter group' established in 2008. The charter group was a network of national public health institutions, financed by the Commission and tasked with the coordination of surveillance between national centres of disease control.

The ECDC has narrow legal capacities (i.e., information gathering and risk assessment) and limited real competences defined as staff and financial resources. Just before the Covid-19-pandemic hit Europe at the beginning of 2020, the ECDC had 286 employees and an annual budget of EUR 60.5 million. In comparison, the US Center for Disease Control and Prevention (US CDC) has legal powers and large resources, counting 10.939 employees and an annual budget of USD 8839.9 million in 2020, with staff working across the globe to detect and control outbreaks at their source.[8]

The existence of epidemiological centres in the member states was the main reason for giving the ECDC limited resources. These national centres were seen as essential partners in managing surveillance networks, training actions, and intervention teams. It was envisaged that the ECDC would work in *equal partnership* with national public health institutions.[9]

Shortly after its creation, the ECDC had to deal with the 2009 H1N1 influenza (swine flu) – the first biggest health crisis facing the EU after SARS. The outbreak prompted several member states to update and revise their national pandemic preparedness plan. In the words of the ECDC's director, '" Unfortunately", this pandemic was very mild, leading several member states to think that their [preparedness] plan was fine and that they could cope with pandemics'.[10]

The H1N1 influenza did not alter the ECDC's formal competences but led to a new legal framework in the EU, the 2013 Decision on cross-border health threats[11], according to which member states must report every three years on their pandemic preparedness status. The decision formalised the existence of the Health Security Committee (HSC) and

[7] Dereulle, T. & Engeli, I. (2021). The COVID-19 crisis and the rise of the European Centre for Disease Prevention and Control (ECDC), *West European Politics*, 44(5-6), 1-25

[8] US Centers for Disease Control and Prevention, FY 2021 President's Budget https://www.cdc.gov/budget/documents/fy2021/FY-2021-CDC-Budget-Detail.pdf (accessed 13 December 2021)

[9] Regulation (EC) No 851/2004 establishing a European Centre for disease prevention and control, available at https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=celex%3A32004R0851 (accessed 13 December 2021)

[10] The ENVI committee's annual exchange of views with ECDC Executive Director in the European Parliament, 16 March 2021, available at https://multimedia.europarl.europa.eu/da/webstreaming/envi-committee-meeting_20210316-0900-COMMITTEE-ENVI (accessed 7 January 2022)

[11] Decision No 1082/2013/EU of the European Parliament and of the Council of 22 October 2013 on serious cross-border threats to health and repealing Decision No 2119/98/EC Text with EEA relevance, available at https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A32013D1082 (accessed 7 January 2022)

strengthened its role. This committee has been in place, informally, since 2001 after the 9/11 and anthrax attacks in the US and consists of representatives from the member states' national health authorities. Its mandate is to strengthen coordination between member states, share best practices and information on national preparedness activities, and coordinate responses to health emergencies. Since the outbreak of Covid-19, the committee has met over 80 times to exchange information and develop common positions, often based on advice from the ECDC.

The ECDC's performance during the Covid-19 outbreak

The ECDC began to monitor Covid-19 in January 2020 after the WHO had become aware of the new virus on 31 December 2019 following a report of several cases of 'viral pneumonia' in Wuhan. In its first published Threat Assessment Brief on 9 January 2020, the ECDC considered the likelihood of the spread of Covid-19 to the EU low. It also assessed that the risk of further spread within the EU, should a case be identified, was low.[12]

On 24 January 2020, the first case of Covid-19 was discovered in the EU; yet the ECDC assessed the risk for healthcare system capacity in the EU to be low to moderate. In a similar vein, the Commission's Directorate-General for Health and Food Safety (DG SANTE) concluded on 27 February 2020 that EU member states had a strong level of preparedness in place, based on a survey conducted with the member states. On 2 March 2020, the ECDC changed its risk assessment and now regarded the risk associated with Covid-19 infection and the spread of the virus to be moderate to high.

It quickly became apparent that both the EU and its member states were unprepared and that the ECDC had failed to assess the real risk of Covid-19 to Europe. This meant that critical time was lost in detecting the true spread and severity of the virus in Europe, resulting in decision delays and lost lives. The ECDC was unable to provide real-time situational awareness and data supporting early evidence-based decision-making.[13]

Once the true scale of the crisis was apparent, the ECDC took a rather cautious and reactive approach. It largely refrained from giving member states explicit advice on how to tackle the crisis in order not to overstep its mandate as a risk assessing institution. The challenges facing the ECDC were numerous, most notably:

[12] ECDC, Risk Assessments, available at https://www.ecdc.europa.eu/en/all-topics-z/threats-and-outbreaks/risk-assessments (accessed 7 January 2022)
[13] European Commission, Communication, 'Building a European Health Union: Reinforcing the EU's resilience for cross-border health threats', COM(2020) 724 final, 11 November 2020, p. 4, available at https://ec.europa.eu/info/sites/info/files/communication-european-health-union-resilience_en.pdf (accessed 13 December 2021)

1) The ECDC struggled to oversee fundamental disease surveillance because it received **incomplete and incomparable data** from member states that used diverging reporting methods.
2) **A reactive and cautious approach** on part of the ECDC instead of a more proactive response with practical hands-on advice and support to member states based on best available evidence.
3) **A strict interpretation of the ECDC's mandate** as a risk assessing agency rather than that of risk management.

Incomplete and incomparable data

The pandemic revealed the limitations of the ECDC's current surveillance system, which is only as effective as the data that feeds them.[14] Member states' requirement to report relevant, complete, and timely data to the ECDC has proven particularly difficult to enforce, especially in situations where some member states lack the necessary surveillance and reporting capacities. Evidently, access to timely and complete data is crucial for ECDC's ability to undertake rapid risk assessments that support real-time situational awareness and early evidence-based decision-making.

Covid-19 has shown that the ECDC is not in equal partnership with the member states' epidemiological centres as envisaged when setting up the ECDC. Instead, the relationship is one of power asymmetry[15] where the ECDC is dependent on national health authorities to provide it with data. The ECDC does not have the power to gather, or quality assure the source of surveillance and data reporting within member states. The ECDC does provide guidelines on data collection but has no authority to enforce its standards for data reporting. The ECDC obtains data and information from four main sources:

- *The European Surveillance System* (TESSy): Member states upload data on infectious diseases under European surveillance using standardised formats.
- *The Early Warning and Response System of the EU* (EWRS): An IT-platform operated by the ECDC, where member states and the Commission must notify public health events, meeting certain criteria, within 24 hours. The platform serves to quickly report and exchange information on emerging threats. Access and postings are confidential and only accessed by the ECDC, national authorities, and DG SANTE.

[14] European Commission (2021) Drawing the early lessons from the Covid-19 pandemic, Communication from the Commission, COM(2021) 380 final, available at https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52021DC0380 (accessed on 7 January 2022)
[15] European Ombudsman, Decision in strategic inquiry OI/3/2020/TE on how the ECDC gathered and communicated information during the COVID-19 crisis, p. 10, available at https://www.ombudsman.europa.eu/en/decision/en/137815 (accessed 13 December 2021)

- *Surveys conducted by the ECDC*: The ECDC may conduct surveys on its own initiative or upon request from the Commission, where it asks member states for information not covered by TESSy. Throughout the pandemic, the ECDC has experienced a low and delayed response rate from member states.
- *Epidemic intelligence screenings* conducted by the ECDC by daily monitoring official websites from public health authorities within and beyond Europe.

The ECDC particularly focuses on indicator-based surveillance that primarily relies on data reported by member states via TESSy. For instance, member states are requested to report weekly surveillance data on the total number of cases and tests of Covid-19, number of tested among hospitalized patients with severe acute respiratory illness by age groups.

The ECDC issues guidelines to the member states on how to collect and report data, such as a common case definition for Covid-19 and a standardised set of variables to be followed. The ECDC's disease networks[16] and advisory forum (composed of members from technically competent bodies in member states) serve as important fora to foster a shared understanding of how data should be reported. Despite of this, member states regularly fail to report on all indicators/variables requested by the ECDC (e.g., testing rates, test positivity, and hospital, and intensive care unit admissions) and there is limited data from the regional level reported in TESSy.[17]

There are significant discrepancies between the data reported in TESSy by member states and the ECDC's epistemic intelligence screenings, using web-scanning tools. For instance, in the early days of the pandemic (ultimo March 2020), there were 79.194 Covid-19 cases reported in TESSy, whereas the ECDC had identified 265.500 cases through its epistemic intelligence screenings. The examples of data incomparability are numerous: member states report the cause of death differently (i.e., did a patient die with or of Covid-19?), member states disregard the commonly agreed case definition of Covid-19[18], and member states use different testing strategies.

Member states follow different methods when conducting their Covid-19 surveillance, which makes it difficult to compare country data. Few countries use population-based surveillance methods, whereby a specific population is monitored, such as the whole

[16] ECDC's partnerships and networks, available at https://www.ecdc.europa.eu/en/about-us/ecdcs-partnerships-and-networks (accessed 7 January 2022)
[17] Report of the 36th Health Security Committee, 17 September 2020, available at https://ec.europa.eu/health/sites/default/files/preparedness_response/docs/ev_20200917_sr_en.pdf (accessed 7 January 2022)
[18] Report of the 29th Health Security Committee, 24 July 2020, available at https://ec.europa.eu/health/sites/default/files/preparedness_response/docs/ev_20200724_sr_en.pdf (accessed on 7 January 2020)

population of a country or a region. There is currently little the ECDC can do to ensure full data comparability across the EU.

The ECDC made protocols early on how to roll out testing to have representative samples as well as comparable data, but in the end, it is a national decision to decide on a suitable testing strategy. Member states differ on who they test and how much they test, which influences the incidence rate and total number of cases detected.[19] In Austria, for instance, citizens have on average been tested 18 times between ultimo March 2020 and January 2022, whereas in the vast majority of member states the number is less than five.[20] This makes it impossible to know if a country has few reported cases due to low transmission or limited testing.

The patchwork of testing strategies hinders a full overview of the epidemiological situation in the EU and does not provide a suitable basis for decision-making. For example, 'the surveillance data used to put travel measures in place was not comparable between the countries [...]. Based on non-comparable data, quite far-reaching decisions have been made'[21].

The same incomplete and incomparable data was used to enact border closures during the first six months of the pandemic, despite the ECDC vehemently advising against the effectiveness of border closures. Austria was the first country to close its national border with Italy against the virus on 11 March 2020. 11 other member states closed its borders shortly after. These border closures hit the free movement of services particularly hard, as the service sector is dependent on being able to move staff seamlessly across borders.[22] The ECDC's position on borders was clear and consistent, 'human to-human transmitted respiratory virus with global distribution cannot be controlled by means of border closures'.[23] Only in mid-June 2020 was the freedom of movement within the EU re-established.

The difficulty in obtaining data needed to steer the response to Covid-19 in an optimal way has uncovered the inadequacy of the surveillance systems in the EU. Even the ECDC temporarily dropped its traffic-light coloured maps showing the level of contagion in Europe and the world, ostensibly due to its data inadequacies.

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[19] Report of the 30th Health Security Committee, 6 August 2020, available at https://ec.europa.eu/health/sites/default/files/preparedness_response/docs/ev_20200806_sr_en.pdf (accessed on 7 January 2022)

[20] ECDC, data on testing, available at https://www.ecdc.europa.eu/en/publications-data/covid-19-testing (accessed on 7 January 2022)

[21] The ENVI committee's annual exchange of views with ECDC Executive Director in the European Parliament, 16 March 2021, available at https://multimedia.europarl.europa.eu/da/webstreaming/envi-committee-meeting_20210316-0900-COMMITTEE-ENVI (accessed 7 January 2022)

[22] Tænketanken Europa, #GenstartEU 2, Den Europæiske improvisator, 24 June 2022, available at http://thinkeuropa.dk/sites/default/files/genstart_eu_rapport_02_enkeltsider.pdf (accessed 7 January 2022)

[23] ECDC (2020). Rapid Risk Assessment: Coronavirus Disease 2019 (Covid-19) in the EU/EEA and the UK – Eleventh Update: Resurgence of Cases, available at https://www.ecdc.europa.eu/en/publications-data/rapid-risk-assessment-coronavirus-disease-2019-covid-19-eueea-and-uk-eleventh (accessed 7 January 2022)

Undoubtedly, the quality of the data relies on the system it is coming from, and the surveillance strategy used in member states, such as how to collect data and who to test. These difficulties resulted in initial delays to detect the ongoing community transmission and widespread transmission of Covid-19 before any containment measures were put in place, which contributed to Europe's first, serious corona-wave in Spring 2020.

A reactive and cautious approach

The ECDC's founding regulation does not distinguish between responsibilities in "peacetime" and during a public health emergency. An external study on the ECDC's response to Covid-19[24] shows that ECDC's crisis response was reactive and lacked a clear strategic direction due to both a high workload from incoming requests from member states and a lack of proper coordination with the Commission on the direction to take. Furthermore, the ECDC's attempt to align itself with the WHO also delayed its response.

Several member states thought that the ECDC's output were too technical and scientific to provide decision-making guidance. They would have liked the EDCC's guidance to be more practically applicable and to proactively give advice on actions to take even considering scientific uncertainty. For example, the ECDC's recommendation on the use of personal protective equipment came at a time when certain PPEs were in shortage and advice on an alternative plan would have been beneficial.[25]

The ECDC has also been cautious not to engage in benchmarking and best practices between member states. For instance, at no point has the ECDC or the HSC assessed which Covid-19 restrictions worked best to limit the spread of the virus. Throughout the entire pandemic, member states have had very different types of restrictions in place.

The external evaluation of the ECDC's performance in 2020[26] suggested that the ECDC needs to bridge the gap between its scientific findings and political guidance for policymakers through more practical and timely recommendations. This requires a clear understanding of different audience needs (i.e., the public, health professionals, and decision-makers) and publication of the best available evidence at a given point. This suggests that there is room for the ECDC to provide early advice for decision-makers and to assess and disseminate cross-country learnings between member states on the most

[24] McKinsey, External strategic and performance analysis of ECDC response to the Covid-19 pandemic, November 2020, available at https://www.ecdc.europa.eu/sites/default/files/documents/ECDC_report_on_response_Covid-19.pdf (accessed 7 January 2022)
[25] Interview with national representative of the ECDC's advisory board, September 2021
[26] McKinsey, External strategic and performance analysis of ECDC response to the Covid-19 pandemic, November 2020, available at https://www.ecdc.europa.eu/sites/default/files/documents/ECDC_report_on_response_Covid-19.pdf (accessed 7 January 2022), Chapter 3

effective responses without encroaching on member states' competences in health.[27] Perhaps this role will also make the ECDC more visible to European citizens.

Despite the ECDC's key role in data surveillance within Europe, it does not enjoy the same media presence nationally as national health institutes and virologist, although significant differences exist between countries. In many EU countries, the ECDC is mainly referred to as a data source, such as the number of reported cases across the EU. For instance in Germany, the ECDC was mentioned 1,585 times and the German Robert-Koch-Institute was mentioned 79,112 times between January and September 2020 in a national press analysis (covering printed and on-line magazines and newspapers, periodicals and specialist magazines or publications). [28] Few citizens have ever heard of the ECDC, and the EU does not have a 'federal' mouthpiece in public health like the head of the European Central Bank.[29] Instead, several national virologists have become well-known nationally and media darlings (such as Søren Brostrøm in Denmark, Anders Tegnell in Sweden, Christian Drosten in Germany, and Jaap van Dissel in the Netherlands).

A strict interpretation of the ECDC's mandate

The ECDC's role is to provide risk assessment rather than engaging in direct risk management, which is a national competence. Compared to similar agencies elsewhere, the ECDC's mandate as a risk assessor organisation is rather strict. Many other centres for disease control have the mandate to act as a risk manager to various degrees. For example, the US CDC is responsible for keeping stockpiles and distributing scarce supplies. Similarly, the Korean DCA took on a risk manager role during Covid-19 by assisting with prevention, containment, and quarantine measures. [30]

The distinction between risk assessment and risk management has always been a bone of contention in the EU. In the early days of the ECDC's existence, even the specific term used to refer to the ECDC's advice was controversial. For instance, member states discussed whether the ECDC's advice should be referred to as 'guidelines or 'guidance'.

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[27]Pwc, Third independent external evaluation of the ECDC in accordance with its Founding Regulation, September 2019, available at https://www.ecdc.europa.eu/en/publications-data/third-external-evaluation-ecdc-2013-2017 (accessed 7 January 2022)

[28] McKinsey, External strategic and performance analysis of ECDC response to the Covid-19 pandemic, November 2020, available at https://www.ecdc.europa.eu/sites/default/files/documents/ECDC_report_on_response_Covid-19.pdf (accessed 7 January 2022), Chapter 3

[29] Van Middelaar, L., (2021). Pandemonium. Saving Europe, Newcastle upon Tyne: Agenda Publishing Ltd., p. 129

[30] McKinsey, External strategic and performance analysis of ECDC response to the Covid-19 pandemic, November 2020, available at https://www.ecdc.europa.eu/sites/default/files/documents/ECDC_report_on_response_Covid-19.pdf (accessed 7 January 2022), Chapter 5

Member states preferred the term 'guidance', as the word 'guidelines' was regarded as carrying an undertone of obligation.[31]

The ECDC has always walked on its tiptoes and interpreted its mandate in a strict and narrow manner as solely a risk assessor that refrains from telling member states what to do.[32] Throughout the Covid-19 pandemic, however, several member states and the Commission wanted the ECDC to become more engaged in risk management. There are several examples of the ECDC slowly crossing the fine line between risk assessment and risk management, as further exemplified below.

In February 2020, the ECDC published guidelines for the use of non-pharmaceutical interventions. The very use of the word guidelines is noticeable given member states previous reluctance to use the term. In early March 2020, the ECDC updated risk assessment to the HSC included five detailed response scenarios for member states to choose from with the two most far-reaching scenarios including general lockdowns. The explicitness of these guidelines shows that the ECDC increasingly engages in advice on risk management – although it remains in the hands of the member states to decide whether, or not, to follow them.

Once lockdowns started to enter into force across Europe from March 2020, the Commission requested the ECDC advice on several risk management measures, including guidance on the rational use of PPE under scarcity conditions, overview reporting on the readiness of national crisis emergency systems, and guidance on health systems contingency planning to address possible containment scenarios.[33]

During the pandemic, the ECDC became increasingly involved in giving the European Commission and member states advice on containment measures, particularly lockdowns and the opening and closing of borders. Since May 2020, the ECDC started to attend meetings in the Justice and Home Affairs Council, indicating a role for the ECDC in advising member states on border closures and openings. The Commission's recommendations on free movement within the EU and border restrictions were based on the ECDC's input and advice.[34]

[31] Deruelle, T. & Engeli, I. (2021). The COVID-19 crisis and the rise of the European Centre for Disease Prevention and Control (ECDC), *West European Politics*, 44(5-6), 1-25

[32] Pwc, Third independent external evaluation of the ECDC in accordance with its Founding Regulation, September 2019, available at https://www.ecdc.europa.eu/en/publications-data/third-external-evaluation-ecdc-2013-2017 (accessed 7 January 2022)

[33]Report of the 11th Health Security Committee, 13 March 2020, available at January 2022)

[34] Deruelle, T. & Engeli, I. (2021). The COVID-19 crisis and the rise of the European Centre for Disease Prevention and Control (ECDC), *West European Politics*, 44(5-6), p.14

On 18 May 2020, France and Germany jointly proposed to establish an EU Health Task Force within the ECDC.[35] This was followed by a statement from Denmark, France, Germany, Spain, Belgium, and Poland on 10 June 2020 to expand the ECDC's mandate 'to coordinate with national health authorities, prevention and reaction plans against future epidemics within a future EU health task force'[36], which gained consensus among member states a week later.[37] These calls indicate that the ECDC's mandate is evolving and is slowly crossing the line between risk assessing and risk management. Many of these ideas were introduced in the Commission's proposal to strengthen the ECDC's mandate, put forward on 11 November 2020.

A revised ECDC regulation: A reinforced mandate?

On 30 November 2021, the European Parliament (EP) and the Council reached a final compromise in trilogue on a new regulation that strengthens the ECDC's mandate and put the lessons of the pandemic into legal changes. This compromise was endorsed by the EP's public health (ENVI) committee on 13 January 2022 and is now awaiting formal approval by the EP's plenary in February and the Council before it will enter into force.

With the new regulation, the ECDC's resources and competences are beefed up. 73 new positions are foreseen in 2022 and an extra €157 million allocated to the ECDC in the current seven-year multiannual financial framework 2021-27. In the words on the ECDC's director, these new resources 'sounds like a lot but with the expanded focus and new threats, it is tight'.[38]

The new regulation includes plans to develop state-of-the-art surveillance of future outbreaks, improve joint preparedness and response planning with member states, stronger ECDC guidance and member state support during emergencies, including through the assistance of a standing, ready-to-be-deployed EU Health Task Force. The ECDC's mission and tasks are expanded in five key areas:

1. Increased situational awareness through integrated and digitalised systems enabling real-time epidemiological surveillance

[35] Ministère de l'Europe et des Affaires étrangères (2020). European Union – French-German Initiative for the European Recovery from the Coronavirus Crisis, available at https://www.diplomatie.gouv.fr/en/coming-to-france/coronavirus-advice-for-foreign-nationals-in-france/coronavirus-statements/article/european-union-french-german-initiative-for-the-european-recovery-from-the (accessed 7 January 2022).
[36] Momtaz, R., Deutsch, J., & Bayer, L. (2020). National Capitals Question EU's Pandemic Preparedness, Politico, 10 June 2020, available at https://www.politico.eu/article/eu-national-capitals-question-coronavirus-pandemic-preparedness/ (accessed 7 January 2022)
[37] Bundesgesundheitsministerium (2020). 'Informal Meeting of Health Ministers', available at https://www.bundesgesundheitsministerium.de/en/press/2020/informal-meeting.html (accessed 7 January 2022)
[38] CEPS Ideas Lab, Towards a European Health Union, 31 May 2021, available at https://www.youtube.com/watch?v=A_OWuVMneD4&t=2572s (accessed 7 January 2022)

2. Preparedness and response planning, reporting, and auditing
3. Provision of concrete, non-binding EU-level and country-specific recommendations and risk management
4. Capacity to mobilise and deploy the EU Health Task Force to assist local response to outbreaks of communicable disease in member states and third countries
5. Coordination of two new EU networks: 1) a network of reference laboratories for crisis-relevant advice on new pathogens and 2) and a network for substances of human origin, e.g., tissues, cells, and blood.

First, the ECDC is mandated with updating its current epidemiological surveillance systems to rely less on human input from member states and more on data from secure, interoperable digital platforms and applications. These platforms/applications should enable the use of digital technologies, such as artificial intelligence and computer modelling and simulation in the compilation and analysis of data. The pandemic has demonstrated that even manual reporting of simple statistics, such as infection data, number of intensive care beds, and availability of health professionals, within the EU was difficult.

The EU does not, currently, have a clear health data architecture and few member states have a comprehensive health data governance system in place at the national level. The European Commission's upcoming proposal on setting up a European Health Data Space[39] infrastructure, scheduled for the first quarter of 2022, will facilitate and regulate secondary use of electronic health records. It will be an integral part of building a European Health Union and provide timely access to health data for research and policy-making purposes that will also be joined up with the ECDC's future digital surveillance systems. The aim is to have an interoperable data access infrastructure in place by 2025 to facilitate secure cross-border analysis of health data.[40] The main technology to be developed and used is the secondary use of electronic health records' data. These are under development or in use in several countries, but not standardised.

The future digitalisation of integrated surveillance systems is likely to offset some of the challenges faced by the ECDC during the pandemic concerning incomparable, delayed, and incomplete data reporting from member states. However, developing these systems is, in the words of the ECDC's director, 'a massive endeavour and will not be in place immediately, but will take time to be developed'.[41] This means that the current situation

[39] The European health data space will (1) promote safe exchange of patients' data, (2) support research on treatments, medicines, medical devices, and outcomes, (3) encourage the access to and use of health data for research, policymaking, and regulation, with a trusted governance framework and upholding data-protection rules, (4) support digital health services, and (5) clarify the safety and liability of artificial intelligence in health.
[40] European Commission, press release, Commission and Germany's Presidency of the Council of the EU underline importance of the European Health Data Space, 11 November 2020, available at https://ec.europa.eu/commission/presscorner/detail/en/IP_20_2049 (accessed on 7 January 2022)
[41] Presentation by ECDC director, Dr Andrea Ammon, CEPS Ideas Lab, Towards a European Health Union, 31 May 2021, available at https://www.youtube.com/watch?v=A_OWuVMneD4&t=2572s (accessed 7 January 2022)

of indicator-based data provided to the ECDC from the member states will continue to be the ECDC's main data source in the coming years with all the problems they present.

Second, the new regulation tasks the ECDC to work closely with member states to monitor health systems' capacities to detect, prevent, respond to, and recover from infectious disease outbreaks, as well as identify gaps, and provide science-based recommendations for the strengthening of health systems. Meaningful indicators of the state of preparedness still needs to be developed together with the member states to allow the ECDC to assess how prepared a country is.

The ECDC's scientific and technical support to member states is also strengthened, for instance through targeted training and knowledge exchange activities for healthcare/public health staff to provide knowledge and skills. This is envisaged to help member states develop and implement their national preparedness plans (with recommendations and scrutiny from the EU), implement activities to strengthen crisis preparedness, and surveillance capacities.

Third, the new regulation enables the ECDC to formulate recommendations to both the EU's and member states' public health crisis preparedness plans for adoption by the HSC and to facilitate self-assessments and external evaluation of these plans. The ECDC and the HSC will use 'peacetime' to ensure preparedness of member states by setting and following up on recommendations of crisis planning and preparedness guiding each member state.

The ECDC's mandate has until now always ended at surveillance and any previous suggestions for the ECDC to provide recommendations on national crisis preparedness and response have been a taboo. The Covid-19 pandemic has changed this, albeit to a limited degree. The ability for the ECDC to suggest options for crisis response to member states and to provide suggestions for improvements to national preparedness plans is, therefore, really something new. However, it was particularly important for the Council to spell out several places in the final text that all recommendations, advice, guidance, or opinions made by the ECDC are non-binding.

Fourth, the ECDC's ability to assist member states with local responses to disease outbreaks, collect field data, and provide science-based recommendations on response to health threats is improved through the new, permanent EU Health Task Force. This task force consists of the Centre's staff and experts from Member States, fellowship programmes and international and non-profit organisations. The task force shall assist with requests for preparedness and response planning, local response to outbreaks of infectious diseases and after-action reviews in member states and third countries, in cooperation with the WHO. The Council secured in the final legislative text that this task force should be based on profound country knowledge achieved through input from

national experts, based on regular secondment mechanisms between the Centre, the Commission, member states' experts, and international organisations.

Last, the EU's laboratory capacity is strengthened with the establishment of the EU network of reference laboratories, responsible for alignment on diagnostics, testing methods, training procedures, and use of tests. The aim is to ensure uniform surveillance, notification, and standardised procedures for disease reporting, as well as strengthening the quality of testing and surveillance. The network will, for instance, help with the validation of new tests, so that the EU avoids repeating the situation during Covid-19, where tests were thrown on the marked in each member states without an EU-wide validation system in place. The network will also assist member states with developing their detection and sequencing capacities, especially for those countries that do not have sufficient capacities.

Furthermore, the ECDC will get a stronger mandate for global collaboration. The Covid-19 pandemic has emphasised the importance of strong international collaboration for sharing data and knowledge. For example, by the time Europe was dealing with the first Covid-19 wave, Asian countries were already recovering from their first wave. This highlights the necessity to have contacts with centers of diseases worldwide to learn how other countries impacted before Europe have managed.

Like SARS and H1N1 crises, Covid-19 has not led to a major overhaul of the EU's health security framework, mainly because public health is a national competence. The updated ECDC regulation does not confer any regulatory powers on the Centre. Despite of this, the renewed mandate goes a long way to strengthen the ECDC within the confines of the Treaties. In the new regulation, the ECDC can issue non-binding recommendations and suggest options for risk management, previously a no-go area for the ECDC. Even during the pandemic, the ECDC's role was gradually and informally expanding to the management of health threats, which this regulation now formalises.

The new regulation does not, however, solve all the problems facing the ECDC during the pandemic immediately, not least because the EU's health security framework is still based on non-binding intergovernmental arrangements. Several aspects depend on the ECDC's future role in practice, the member states' willingness to share data and embrace EU recommendations, and the development of new digital surveillance systems. As indicated below, there it still room for improvement.

Room for improvement

Risk assessment:

- The ECDC needs to **receive more harmonised and timely data** from the member states. The ECDC's indicator-based surveillance still relies on member state reported data, meaning that the issue of incomplete, incomparable, and delayed data reporting is likely to persist.
- **More digitalised surveillance systems** will help improve the ECDC's epidemiological surveillance, but these systems will take years to be developed.
- The ECDC needs **stronger international tie**s to other CDCs worldwide to share surveillance data and knowledge.
- In the long term, it may be relevant to discuss if harmonisation of data collection and reporting between member states is necessary to ensure the desired level of data comparability.

Risk management:

- The ECDC contributes to **cross-country learnings & best practices**, in collaboration with the HSC. The ECDC could assess and disseminate cross-country learnings between member states on the most effective responses without overstepping member states' competences.
- The ECDC's **guidance needs to be more practically applicable** and proactively guide decision-making even in situations of scientific uncertainty. This also means providing second-best options if the ECDC's desired option is unfeasible.
- A **clear prioritisation** of tasks during a crisis, such as incoming requests from member states.
- Ability to draw on an **emergency response workforce** (more personnel) in crisis situations, including more crisis trained ECDC staff.

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